REMARKS

The above amendments and these remarks are responsive to the Office action dated October 19, 2006. Claims 1–11, 13–20, 23, and 26–28 are pending in the application. Claims 1–11, 13–20, 23, and 26–28 are rejected. By way of the present amendment, claims 1, 9, 11, 18 and 28 have been amended, claim 26 has been cancelled, and new claims 29–31 have been added. In view of the amendments above, and the remarks below, applicant respectfully requests reconsideration of the application under 37 C.F.R. § 1.111 and allowance of the pending claims.

Rejections under 35 U.S.C. § 112

Amended claim 9 depends from claim 2, which provides sufficient antecedent basis for the element "orifices" recited in claim 9. Accordingly, applicant respectfully requests that the rejection of claim 9 under 35 U.S.C. § 112 be withdrawn.

Rejections under 35 U.S.C. §§ 102 and 103

Claims 1, 6, 7, 18 and 23 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Hauschild et al. (U.S. Pat. No. 6,905,475). Claims 2–5 and 8–10, which depend directly or indirectly from claim 1, claim 11 and claims 13–17, which depend directly or indirectly from claim 11, stand rejected under 35 U.S.C. § 103 as being unpatentable over Hauschild et al. in view of Paskar (U.S. Pat. No. 6,623,449). Claims 19, 20 and 26–28, which depend directly or indirectly from claims 1 and 18, stand rejected under 35 U.S.C. § 103 as being unpatentable over Hauschild et al. in view of Kollias et al. (U.S. Pat. No. 6,251,099). Applicant disagrees with the rejections, but has nonetheless made certain claim amendments to clarify what Applicant regards as the invention.

Claim 1 and its Dependent Claims

Amended claim 1 recites a needle-free jet injection device that includes, amongst other structure, "an ejection mechanism adapted to eject the fluid from the fluid reservoir through the end effector and out of the injection orifice at a pressure between about 643 psig and about 2001 psig." In contrast, Hauschild et al. does not disclose, teach, or suggest an ejection mechanism adapted to eject the fluid from the fluid reservoir through the end effector and out of the injection orifice at a pressure between about 643 psig and about 2001 psig.

The Examiner has asserted that Hauschild et al., in Figs. 9 and 10 and at col. 6, line 35 through col. 7, line 27, discloses an ejection mechanism in which the injection pressure can be adjusted and selected. However, Applicant respectfully asserts that, regardless of whether Hauschild et al. discloses an ejection mechanism in which the injection pressure can be adjusted and selected, Hauschild et al. does not disclose, teach, or suggest an ejection mechanism that is capable of generating pressures within the range of about 643 psig to about 2001 psig, as recited in amended claim 1.

As an initial matter, Hauschild et al. does not disclose, teach, or suggest any specific pressures or pressure ranges. Rather, Hauschild et al. merely makes reference to "high pressure" (col. 5, line 59), "limit[ing] injection pressures to predetermined or desired levels" (col. 6, lines 37–38), "unacceptably high pressures" (col. 6, line 40), and "prevent[ing] injection pressures from exceeding acceptable levels" to prevent "extravasation" (col. 6, lines 49–54). Applicant respectfully asserts that none of these statements disclose, teach, or suggest an ejection mechanism that is capable of generating pressures within the range of about 643 psig to about 2001 psig, as recited

in amended claim 1.

Furthermore, Applicant respectfully asserts that Hauschild et al. does not disclose, teach, or suggest an ejection mechanism that is even capable of achieving such pressures. In particular, the surgical devices and kits disclosed in Figs. 4, 5, 9 and 10 and discussed at col. 6, line 35 through col. 7, line 27 of Hauschild et al. are all based on a standard hand-actuated syringe 86, as shown most clearly in Fig. 4. Hauschild et al. does not disclose, teach, or suggest any other source of ejection and/or injection pressure. As set forth in the Declaration of Keith K. Daellenbach, submitted herewith pursuant to 37 C.F.R. § 1.132, standard hand-actuated hypodermic syringes, such as the one illustrated at reference number 86 in Figs. 4, 5, 9 and 10 of U.S. Pat. No. 6,905,475 to Hauschild et al., are only capable of generating pressures that are significantly lower than the lower end of the needle-free pressure range of about 643 psig to about 2001 psig recited in amended claim 1. In particular, the upper end pressures achievable with hand actuated (i.e., with typical human hand strength) standard hypodermic syringes depend on the size of the syringe and range from 229 psig for a 3 mL hypodermic syringe to 98 psig for a 10 mL hypodermic syringe. Therefore, standard hypodermic syringes, the only source of ejection and/or injection pressure disclosed, taught or suggested in Hauschild et al., are not even capable of generating pressures anywhere near the pressure range of about 643 psig to about 2001 psig recited in amended claim 1. Accordingly, Hauschild et al. does not disclose, teach, or suggest an ejection mechanism adapted to eject the fluid from the fluid reservoir through the end effector and out of the injection orifice at a pressure between about 643 psig and about 2001 psig, as recited in amended claim 1.

With regard to Kollias et al., Applicant respectfully asserts that Kollias et al. does not disclose, teach, or suggest a needle-free jet injection device, as recited in amended claim 1. An "injection device" refers to a device that is capable "injecting" something. Merriam-Webster's Online Dictionary defines "inject" as meaning "to introduce into something forcefully" or "to force a fluid into (as for medical purposes)" {http://www.m-w.com/dictionary/inject}. In contrast, Kollias et al. discloses the use of impulse transients, which are generated by exposing a target material to a pulsed laser beam, to induce a transient increase in the permeability of the epithelial tissue layer such that a compound, which has previously been applied to the surface of the epithelial tissue layer, may more readily diffuse through the epithelial tissue (see col. 4, lines 34–38, and col. 2, lines 3–13 and 18–20). In particular, Kollias et al. discloses temporarily increasing permeability to enhance diffusion. Applicant respectfully asserts that methods to enhance diffusion, as disclosed in Kollias et al., do not disclose, teach, or suggest a needle-free jet injection device, as recited in amended claim 1.

Additionally, Applicant respectfully asserts that Kollias et al. is nonanalogous art because the methods and devices disclosed in Kollias et al. are not in the same field of endeavor, nor are they reasonably pertinent to needle-free jet injection, as required by MPEP § 2141.01(a). The fact the subject matter of Kollias et al. and the present application are within the medical industry is irrelevant to whether they are in the same field of endeavor. Kollias et al. discloses methods and devices to enhance diffusion of compounds through epithelial tissue, which is not in the same field of endeavor as needle-free jet injection. Furthermore, enhancing diffusion of compounds through epithelial tissue is not reasonably pertinent to needle-free jet injection. Accordingly,

Kollias et al. is nonanalogous art that may not be relied upon as a reference under 35 U.S.C. § 103.

Furthermore, Kollias et al. does not disclose, teach, or suggest an ejection mechanism adapted to eject the fluid from the fluid reservoir through the end effector and out of the injection orifice at a pressure between about 643 psig and about 2001 psig, as recited in amended claim 1. As an initial matter, Kollias et al. does not does not disclose, teach, or suggest ejecting fluid. Additionally, the impulse transients disclosed in Kollias et al. have "a peak stress or pressure of about 300 to 2000 bars," (col. 2, lines 63–64). This pressure range corresponds to pressures between 4,351 psi and 29,008 psi. These pressures are significantly higher than the pressure range of about 643 psig to about 2001 psig that is recited in claim 1. Accordingly, Kollias et al. does not disclose, teach, or suggest an ejection mechanism adapted to eject the fluid from the fluid reservoir through the end effector and out of the injection orifice at a pressure between about 643 psig and about 2001 psig, as recited in amended claim 1.

For at least the reasons discussed above, the cited references, alone or in combination, do not disclose, teach or suggest a device as claimed in amended claim 1. Claims 2–10 and 23 contain further limitations that distinguish the cited references. Accordingly, amended claim 1 and its dependent claims patentably distinguish the cited art, and Applicant respectfully requests that the rejections of claims 1–10 and 23 under 35 U.S.C. §§ 102 and 103 be withdrawn.

Claim 11 and its Dependent Claims

Amended claim 11 recites a needle-free jet injection device that includes, amongst other structure, an ejection mechanism that comprises a plunger powered by a

gas cartridge. As discussed above, the only source of ejection and/or injection pressure disclosed, taught or suggested in Hauschild et al. is a standard hand-actuated syringe. A hand-actuated syringe, as disclosed in Hauschild et al., does not include a gas cartridge, as recited in amended claim 11. Furthermore, Paskar also does not disclose, teach or suggest a gas cartridge.

Thus, for at least the reasons discussed above, the cited references, alone or in combination, do not disclose, teach or suggest a device as claimed in amended claim 11. Claims 13–17 contain further limitations that distinguish the cited references. Accordingly, amended claim 11 and its dependent claims patentably distinguish the cited art, and Applicant respectfully requests that the rejections of claims 11 and 13–17 under 35 U.S.C. § 103 be withdrawn.

Applicant has added new claim 29, which depends from claim 11. Support for the new claim can be found throughout the specification as filed and no new matter is added. Applicant believes that claim 11 is now allowable. Claim 29 contains further limitations that distinguish the cited references. Therefore, new claim 29 is allowable for at least the reasons discussed above with respect to claim 11.

Claim 18 and its Dependent Claims

Amended claim 18 recites a needle-free jet injection device that includes, amongst other structure, a rigid end effector that has a blunt distal end and "includes a straight shaft section and a distal section" wherein "at least a portion of a longitudinal axis of the distal section is not collinear with a longitudinal axis of the straight shaft section." In contrast, Hauschild et al. does not disclose, teach, or suggest a rigid end effector that has a blunt distal end and "includes a straight shaft section and a distal

section" wherein "at least a portion of a longitudinal axis of the distal section is not collinear with a longitudinal axis of the straight shaft section."

The Examiner has asserted that Hauschild et al. discloses a rigid end effector that has a blunt distal end at reference number 27 in Fig. 6. Applicant respectfully disagrees. However, Applicant respectfully asserts that, regardless of whether Hauschild et al. discloses a rigid end effector, the cystoscope 27 disclosed in Figs. 2, 4 and 6 of Hauschild et al. is straight. Thus, Hauschild et al. does not disclose, teach, or suggest a rigid end effector that has a blunt distal end and "includes a straight shaft section and a distal section" wherein "at least a portion of a longitudinal axis of the distal section is not collinear with a longitudinal axis of the straight shaft section."

Thus, for at least the reasons discussed above, the cited references, alone or in combination, do not disclose, teach or suggest a device as claimed in amended claim 18. Claims 19–20 and 27–28 contain further limitations that distinguish the cited references. Accordingly, amended claim 18 and its dependent claims patentably distinguish the cited art, and Applicant respectfully requests that the rejections of claims 18–20 and 27–28 under 35 U.S.C. §§ 102 and 103 be withdrawn.

Claim 27, which depends from claim 18, recites a needle-free jet injection device in which the ejection mechanism is configured to provide a rise time to peak pressure of 1.6 milliseconds (msec). In contrast, Kollias et al. discloses rise times between 5 and 15 nanoseconds, which are shorter than the rise time recited in claim 27 by more than five orders of magnitude. The specific rise times disclosed in Kollias et al. are selected to "induce a temporary permeability in epithelial tissue layers," which "increases the diffusion of compounds through these layer" (see col. 3, lines 27–30, emphasis added). When

seeking to determine a suitable rise time to peak pressure on the order of a few milliseconds for use in a needle-free jet injection device, one of ordinary skill in the art would not reasonably be expected or motivated to look to the rise time of an impulse transient that is over 100,000 times shorter. Accordingly, Hauschild et al. and Kollias et al., alone or in combination, do not disclose, teach or suggest a device as claimed in claim 27. For at least this additional reason, Applicant respectfully requests that the rejection of claim 27 under 35 U.S.C. § 103 be withdrawn.

Amended claim 28, which depends from claim 18, recites a needle-free jet injection device in which the peak pressure is between about 643 psig and about 2001 psig. As discussed above, Hauschild et al. and Kollias et al., alone or in combination, do not disclose, teach or suggest a peak pressure between about 643 psig and about 2001 psig, as recited in amended claim 28. Thus, for at least this additional reason, Applicant respectfully requests that the rejection of claim 28 under 35 U.S.C. § 103 be withdrawn.

Applicant has added new claims 30 and 31, which depend from claim 18. Support for the new claims can be found throughout the specification as filed and no new matter is added. Applicant believes that claim 18 is now allowable. Claims 30 and 31 contain further limitations that distinguish the cited references. Therefore, new claims 30 and 31 are allowable for at least the reasons discussed above with respect to claim 18.

CONCLUSION

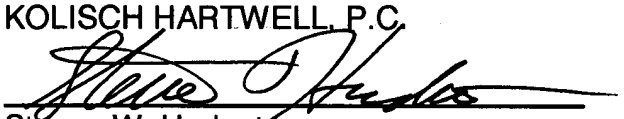
Applicant believes that this application is now in condition for allowance, in view of the above amendments and remarks. Accordingly, applicant respectfully requests that the Examiner issue a Notice of Allowability covering the pending claims. If the

Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 11-1540.

Respectfully submitted,

KOLISCH HARTWELL, P.C.



Steven W. Hudnut
Registration No. 57,786
Customer No. 23581
Attorney/Agent for Applicant(s)/Assignee
520 S.W. Yamhill Street, Suite 200
Portland, Oregon 97204
Telephone: (503) 224-6655
Facsimile: (503) 295-6679

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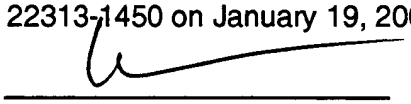

Leia N. Ignacio